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| 10/005,064      | 12/04/2001  | Michael Campbell     | MBHB00-1257-B       | 9564             |

7590

07/14/2003

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 07/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/005,064

Applicant(s)  
Campbell et al.

Examiner  
Deepak Rao

Art Unit  
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 29, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-13, 28-36, 38-47, 62, and 63 ☒ are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 29, 32, 33, 36, 62, and 63 ☒ are rejected.
- 7) ☒ Claim(s) 1, 3-13, 30, 31, 34, 35, and 38-47 ☒ are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 29, 2003 has been entered.

Claims 1, 3-13, 28-36, 38-47, 62 and 63 are pending in this application.

### ***Election/Restriction***

As indicated in the previous office action(s), the examination was limited to a subgenus around the elected species of Example 2. As the elected species was not found in the prior art, as per the guidelines of MPEP § 803.02, the search was expanded to compounds of formula I wherein  $-N(AR^1)(R^2)$  is  $-NH_2$ ; Z is  $-NR^5-$ ;  $(Y^2)_p$  is lower alkylene; and  $m = 0$ , and art was found. All other definitions of the variables and the generic subject matter related to other than the above subgenus is hereby held withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected species.

The rejections of the previous office action are all withdrawn except those that are maintained here below.

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***The following rejections are maintained:***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pomarnaka et al., Chem. Abstract 130:153642 (1998). The instantly claimed compounds read on the reference disclosed compounds, see the compound having RN 220293-61-8 in the copy of the CAPLUS computer search report (provided with previous office action).

Applicant appears to rely on the proviso statements to overcome the rejection, however, there is no proviso statement that effectively excludes the instant reference disclosed compound, wherein  $-N(AR^1)(R^2)$  is  $-NH_2$ ;  $-ZR^4$  is  $-NMe_2$ ; and  $-(Y^2)_p-(T)_n-(Y^1)_m-R^3$  is  $-(CH_2)-S(O)_2-$  (substituted phenyl).

2. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Dollinger et al., Chem. Abstract 128:270618 (1998). The instantly claimed compounds read on the reference disclosed compounds, see the compounds having RN 205532-34-9 and 205532-38-3 (page 27) in the copy of the CAPLUS computer search report (provided with previous office action).

Applicant appears to rely on the proviso statements to overcome the rejection, however, there is no proviso statement that effectively excludes the instant reference disclosed compound, wherein  $-N(AR^1)(R^2)$  is  $-NH_2$ ;  $-ZR^4$  is  $-NH-CH(Me)-(CH_2)_2-(thien-2-yl)$ ; and  $-(Y^2)_p-(T)_n-(Y^1)_m-R^3$  is  $-(CH_2)_2-O-Me$ .

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*The following rejections are under new grounds:*

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29, 32-33 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claims 28 and 32, the term “usefully” (line 2) is redundant and confusing. The claim is clear without the term, see e.g., claim 34.
2. Claim 62 recites the limitation "the therapeutically effective dose includes at least one pharmaceutically acceptable excipient" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 62 is dependent. While the **method** can include an excipient along with the ‘effective dose’ of the compound of formula I, it is not clear how the effective dose includes the excipient. Generally, an excipient is something that is not necessarily ‘effective’ towards the therapeutic action.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Overberger et al., CAOLD Abstract 49:3980e. The instantly claimed compounds read on the reference disclosed compound of RN 403-81-6.
2. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro et al., U.S. Patent No. 2,937,172. The instantly claimed compounds read on reference disclosed compounds, see the formulae in col. 1 and the corresponding Examples in the patent (or the compounds disclosed in the corresponding copy of the computer search report CAOLD Abstract 54:19728f).
3. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Abou-Ouf et al., CAPLUS Abstract 106:4981. The instantly claimed compounds read on the reference disclosed compound, see the compound disclosed in the enclosed copy of the computer search report.
4. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Takematsu et al., CAPLUS Abstract 112:179031. The instantly claimed compounds read on the reference disclosed compound, see the compound disclosed in the enclosed copy of the computer search report having RN 126439-39-2.
5. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lorenz et al., CAPLUS Abstract 127:262706. The instantly claimed compounds read on the reference

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disclosed compound, see all the compounds disclosed in the enclosed copy of the computer search report.

6. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Riebel et al., CAPLUS Abstract 128:282850. The instantly claimed compounds read on the reference disclosed compound, see the compounds disclosed in the enclosed copy of the computer search report havng RN 205937-60-6; RN 205937-66-2; and 205937-67-3.

7. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al., CAPLUS Abstract 132:12332. The instantly claimed compounds read on the reference disclosed compound, see the compound disclosed in the enclosed copy of the computer search report, see RN 251557-98-9.

***Allowable Subject Matter***

Claims 1, 3-13, 30-31 and 34-35 are objected to for containing subject matter drawn to non elected species, but would be allowable if **limited** to the searched and examined subgenus as indicated above.

Claims 28-29, 32-33 and 62 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action **and** limited to the searched and examined subgenus as indicated above.

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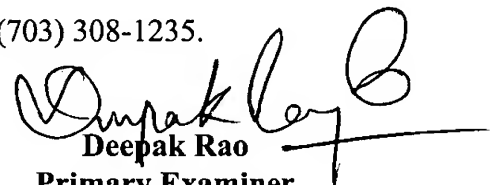
Claims 38-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims **and** limited to the searched and examined subgenus as indicated above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Deepak Rao  
Primary Examiner  
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July 13, 2003